Zopapogene Imadenovec-drba (Papzimeos™)

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

POLICY

INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication

Papzimeos is indicated for the treatment of adults with recurrent respiratory papillomatosis.

All other indications are considered experimental/investigational and not medically necessary.

DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:

- Chart notes, medical record documentation, or laboratory results of all of the following:
  - Presence of laryngotracheal papillomas
  - Histological diagnosis of papilloma confirmed by pathology report
  - Member has documented human papillomavirus (HPV) serotype 6 or 11

PRESCRIBER SPECIALITIES

This medication must be prescribed by or in consultation with an otolaryngologist, pulmonologist, or a specialist in the treatment of recurrent respiratory papillomatosis.

COVERAGE CRITERIA

Recurrent Respiratory Papillomatosis (RRP)

Authorization of 16 weeks (for a one-time treatment course of 12 weeks [4 doses]) may be granted for treatment of recurrent respiratory papillomatosis (RRP) in adults members when all of the following criteria are met:

- Member has a clinical diagnosis of recurrent respiratory papillomatosis defined by all of the following:
  - Presence of laryngotracheal papillomas
  - Histological diagnosis of papilloma confirmed by pathology report
  - Member has documented HPV serotype 6 or 11
- Member has had 3 or more debulking procedures to remove laryngotracheal papillomas in the 12 months prior to treatment with Papzimeos.
- Prescriber attests to both of the following criteria:

  - Surgical debulking of visible papilloma will be performed prior to initial administration to establish minimal residual disease
  - If present, visible papillomas will be removed to maintain minimal residual disease prior to the third and fourth administration of Papzimeos
- Member has not received more than 4 doses (one-treatment course) of Papzimeos.
- Papzimeos will not be used in combination with other medications used for the treatment of RRP (e.g., bevacizumab, cidofovir).
- Member has a negative serology test for hepatitis B (HBV) and hepatitis C (HCV).

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

REFERENCES

1. Papzimeos [package insert]. Germantown, MD: Precigen, Inc.; August 2025.
2. Recurrent respiratory papillomatosis or laryngeal papillomatosis. National Institute on Deafness and Other Communication Disorders. No. 10-4307. September 2017. https://www.nidcd.nih.gov/health/recurrent-respiratory-papillomatosis. Accessed October 7, 2025.
3. Recurrent respiratory papillomatosis. National Organization for Rare Disorders. June 2023. https://rarediseases.org/rare-diseases/recurrent-respiratory-papillomatosis/. Accessed October 7, 2025.

EFFECTIVE DATE 12/31/2025

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